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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,038	02/27/2002	James R. Komorowski	NUTRI.023A	6775

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/090,038	KOMOROWSKI ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 38-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 38-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 7, 38, 39, 41, 42, 44-49, 53 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Rath (US Pat. 6,693,129).

Rath expressly discloses a method of treating high LDL and high triglycerides by administering a composition containing 165 mcg of biotin and 10 mcg of chromium glycinate falling within the scope of applicant's claims (Column 6, lines 34-68, Column 7, Column 8, lines 1-20).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ

594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 190 USPQ 461, 463 (CCPA 1976) (held that there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics). "A `consisting essentially of' claim occupies a middle ground between closed claims that are written in a `consisting of' format and fully open claims that are drafted in a `comprising' format." PPG Industries v. Guardian Industries, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder Co. v. E.I. duPont de Nemours & Co., 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 137 USPQ 893 (CCPA 1963); Water Technologies Corp. v. Calco, Ltd., 7 USPQ2d 1097 (Fed. Cir. 1988).

However, for search and examination purposes, absent a clear indication in the specification of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 48 USPQ at 1355 ("PPG could have defined the scope of the phrase `consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.").

When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989)("Although `consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by `consisting essentially of' language.").

In light of the above, Applicant has not provide sufficient evidence that the use of the phrase "consisting essentially" excludes the other compounds set forth in Rath.

With respect to the amended claim language the amounts of biotin and chromium complex appear to fall within the scope of amounts which Applicant indicates are synergistically effective amounts for raising HDL cholesterol levels, as such, it appears that during the normal course of administering the above composition for the treatment indicated that the method will inherently raise serum HDL cholesterol levels.

Applicant's reliance on PPG Industries is misplace, in that case, there was evidence that even minor changes in color constituted a material change. There is no evidence that a compound which also has a cholesterol lowering effect would constitute a material change in the

invention. Applicant's reliance on Prody and Carberry Corp. v. Land O'lakes, Inc. is also misplaced as it is an unpublished opinion and may not be cited as precedent. Applicant's reliance on American Machine & Foundry Co. v.Ligget & Meyers Tobacco Co. is also misplaced as there is no holding that "consisting essentially of" excluded materials that had a complementary or beneficial effect on tobacco paper. Even if said cases support Applicant's interpretation of the law, Applicant has not provided sufficient evidence that the other disclosed ingredients will materially affect the basic and novel characteristic of Applicant's claimed invention. Based on case law, the addition of the other ingredients must significantly affect serum levels of HDL cholesterol versus biotin and chromium alone. Further, in each of the cases, the products were actually tested to determine that the other components had a material affect on the basic and novel characteristics of the claimed invention. While said ingredients may have an effect on cholesterol levels based on the references provided by Applicant, Applicant has not provided any evidence by actual experimentation that the combination of the other ingredients with biotin and chromium would result in an increase in HDL which is significantly different from biotin and chromium alone.

With respect to Applicant's argument as to inherency, the fact that levels of triglycerides, LDL and HDL are independent risk factors for such disorders as coronary heart disease, does not preclude the determination that individuals which take the prior art composition would benefit from higher HDL levels.

As indicated in the prior Office Action, the rejection herein is based on inherency. As such, absent evidence that the prior art method does not inherently result in increase in HDL levels, the Graham v. John Deere factors are not applicable. Once Applicant provides evidence

that the prior art method would not result in an increase in HDL, then the Graham v. John Deere factors would be applicable. See In re Best, 195 USPQ 430, 433 (CCPA 1977) (Applicant claimed a process for preparing a hydrolytically-stable zeolitic aluminosilicate which included a step of "cooling the steam zeolite ... at a rate sufficiently rapid that the cooled zeolite exhibits a X-ray diffraction pattern ...." All the process limitations were expressly disclosed by a U.S. patent to Hansford except the cooling step. The court stated that any sample of Hansford's zeolite would necessarily be cooled to facilitate subsequent handling. Therefore, a prima facie case under 35 U.S.C. 102 /103 was made. Applicant had failed to introduce any evidence comparing X-ray diffraction patterns showing a difference in cooling rate between the claimed process and that of Hansford or any data showing that the process of Hansford would result in a product with a different X-ray diffraction. Either type of evidence would have rebutted the prima facie case under 35 U.S.C. 102. A further analysis would be necessary to determine if the process was unobvious under 35 U.S.C. 103.); Ex parte Novitski, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of P. cepacia. A U.S. patent to Dart disclosed inoculation using P. cepacia type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.). With respect to Applicant's argument as to dyslipidemia, high LDL and triglycerides would appear to fall within the scope of the limitation dyslpidemia. Any benefit from reducing the number of active ingredients, does not appear sufficient to establish the non-

obviousness of using the combination of ingredients to reduce high LDL and triglycerides. The claims as indicated above to do not require the exclusion of the other active ingredients. Further, before considering any evidence of unexpected results, Applicant must first show that the prior art method would not inherently result in increased levels of HDL.

Claims 7, 38-50, 53, 54 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over McCarty et al. (US Pat. 5,929,066)

McCarty et al. expressly discloses a method for reducing hyperglycemia and stabilizing the level of serum of glucose comprising administering to an individual in need thereof between about 50 and 1000 mcg/day or between about 500 and 1000 mcg/day of chromium as chromic tripicolinate in combination with between about 25 mcg and 200 mg/day or between about 1 mg and 100 mg/day of biotin, where the amounts of chromic picolinate and biotin are selected together to provide a greater than additive effect, where the biotin or chromic tripicolinate can be orally and/or parenterally administered (Claims 1-9) falling within the scope of applicant's claims. It is inherent that reducing hyperglycemia and stabilizing the level of serum of glucose will treat dyslipidemia and increase HDL cholesterol levels (See US Pat. 6,140,304, Column 12, lines 61-66).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See also In re May, 197 USPQ 601, 607 (CCPA 1978). See also Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

Applicant argues that other causes of hyperglycemia and dyslipidemia exist, however, one must look to the population of persons treated by the prior art, i.e. type II diabetics. Applicant's references do not establish that an increase in HDL and normalization of lipids would not result in type II diabetics. Since inherency is established, the burden is on Applicant to show that the prior art method would not result in an increase in HDL before evidence of unobviousness is considered. Applicant argues that an association is not sufficient to establish inherency. However, in In re Novitski there was no evidence provided to show that the prior art method inherently read on the claimed process other than Applicant's own Specification.

Claims 7, 38-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066), each in view of de la Harpe et al. (US Pat. 5,948,772) and Brand-Miller for the reasons of record set forth in the prior Office Actions and in further view of Rath (US Pat. 6,693,129) in further view of Sears (US Pat. 6, 140,304) and the further reasons below.

McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066) were discussed in the prior Office Actions and the same are incorporated herein.

de la Harpe et al., Brand-Miller were discussed in the prior Office Actions and the same are incorporated herein. Further de la Harpe et al. discloses that chromium increases HDL levels (Column 2, lines 30-38).

Rath discloses a composition containing biotin and chromium glycinate which is effective in lowering LDL and triglycerides which can be administered orally or parenterally, and that those skilled in that art would understand that changes can be made and equivalents substituted and that effective amounts may vary depending on variations in patients, durations of

treatment, etc. and that modifications may made to adapt a particular situation and composition of matter (Column 5, lines 45-56, Column 6, lines 36-68, Column 7, Column 9, lines 1-33).

Sears discloses that insulin resistance due to hyperinsulinemia is commonly associated with increased glycosation of hemoglobin due to increased serum glucose levels and that hyperinsulinemia is also associated with increased triglycercides, decreased HDL cholesterol levels and elevated percent body fat (Column 12, lines 60-66).

Examiner has duly considered Applicant's arguments but deems them unpersuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 231 USPQ 375 (Fed. Cir. 1986). Further, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 208 USPQ 871 (CCPA 1981).

de la Harpe discloses that hypercholesterolemia is present in diabetics. (De La Harpe, Column 1, lines 24-36). Diabetics suffer from ineffective insulin and compromised glucose metabolism which leads to hypercholesterolemia. As such, one of ordinary skill in the art would expect that biotin which is known to be effective in controlling the cause of the hypercholesterolemia, i.e. diabetes, hypercholesterolemia which is the result of uncontrolled diabetes would be alleviated by adminstration of biotin. Contrary to Applicant's arguments, the McCarty references do not provide evidence that the activity of biotin is due to a mechanism

independent of the function of insulin. The fact that biotin is effective in type I diabetics does not preclude biotin from acting also by a mechanism which is dependent on the function of insulin. Even if such were the case, Applicant's arguments do not take away from the fact that hypercholesterolemia is a symptom of diabetes, as such, one of ordinary skill in the art would expect that treating the underlying cause, i.e. diabetes, would be effective in treating the symptom, i.e. hypercholesterolemia and that the prior art teaches a composition containing both biotin and chromium which is used to lower LDL and triglycerides. As such, contrary to Applicant's arguments, the effectiveness of biotin in altering serum lipid levels in not found exclusively in Applicant's Specification. Further, the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. In re Linter, 173 USPQ 560 (CCPA 1972); In re Dillon, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). As indicated above, Applicant has provided no evidence that the use of the phrase "consisting essentially of" excludes the one or more of the components in Rath. As such, as indicated above, the prior art does disclose or suggest Applicant's claimed invention. Further, Applicant has provided no evidence that one of ordinary skill art would not be able to develop a method of treatment based on an association between hyperglycemia and lowered HDL levels. Obviousness does not require absolute predictability. Further, inherency can be used in a 103 rejection to reject claims. In re Napier, 34 USPQ2d 1782, 1784 (Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). As such, the prior art method which discloses the administration of biotin and chromium will inherently increase HDL levels.

Applicant amends the claims by adding the limitation "synergistically" and cites to Figures 2 and 14 and pages 15 and 25 of the Specification for supported of this synergistic effect. However, the evidence of synergy is not commensurate in scope with the breath of the claims as only specific amounts are tested. The claims now indicated that the synergistic effect is increase in HDL cholesterol levels. However, it is not clear what amounts of chromium complex and biotin were tested, as such, it is uncertain whether the synergistic activity encompasses the entire ranges of amounts claimed. Whether the unexpected results are the result of unexpectedly improved results or a property not taught by the prior art, the "objective evidence of nonobviousness must be commensurate in scope with the claims which the evidence is offered to support." In other words, the showing of unexpected results must be reviewed to see if the results occur over the entire claimed range. In re Clemens, 206 USPQ 289, 296 (CCPA 1980) (Claims were directed to a process for removing corrosion at "elevated temperatures" using a certain ion exchange resin (with the exception of claim 8 which recited a temperature in excess of 100C). Appellant demonstrated unexpected results via comparative tests with the prior art ion exchange resin at 110C and 130C. The court affirmed the rejection of claims 1-7 and 9-10 because the term "elevated temperatures" encompassed temperatures as low as 60C where the prior art ion exchange resin was known to perform well. The rejection of claim 8, directed to a temperature in excess of 100C, was reversed.). See also In re Peterson, 65 USPQ2d 1379, 1382-85 (Fed. Cir. 2003) (data showing improved alloy strength with the addition of 2% rhenium did not evidence unexpected results for the entire claimed range of about 1-3% rhenium); In re Grasselli, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing

sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims.). Applicant's citation to figure 14 and paragraph 0110 still does not show what amounts were administered.

Even assuming the evidence of synergy is commensurate in scope with the claims, both McCarty '066 and McCarty '401 disclose the combination of biotin and chromium complex results in synergistic effects (McCarty '066, Column 2, lines 56-65; McCarty '401, Column 2, lines 49-57). Further, it is expected from the prior art that the combination of chromium complex and biotin would result in increased HDL cholesterol levels. Further, it does not appear that the amounts claimed as being synergistic are significantly different that which are normally used in the prior art or that the group of individuals having dyslipidemia or raising serum HDL levels and would benefit from increasing serum HDL cholesterol levels are significantly different from the group of individuals having hyperinsulinemia and increased serum glucose levels. As indicated above, one of ordinary skill in the art would expect that the synergistic effect of biotin and chromium on hyperglycemia would have a synergistic effect on HDL levels as one of ordinary skill in the art would expect that treatment of hyperglycemia in type II diabetics would result in increased HDL levels.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Gary Kunz, can be reached at 571-272-0887. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

FIC
March 4, 2006

JOHN PAK
PRIMARY EXAMINER
GROUP 1600